

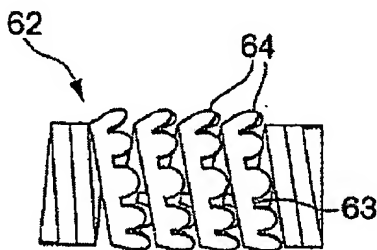
### **REMARKS**

Claims 1-5, 7-11, 14 and 16-25 are currently pending in the application. Claims 3 and 12 have been canceled. Claims 19-12 are withdrawn. Claims 1, 4, 7, 8, 9, 11 and 14 are amended.

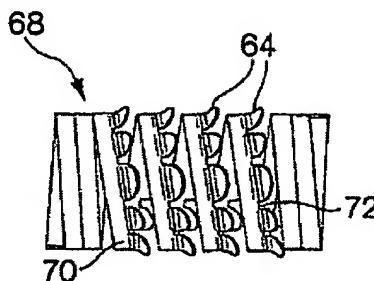
### **APPLICANT'S INVENTION**

Applicant's invention relates to improvements in tissue implants, that is, implants adapted to be embedded within tissue, particularly dynamic tissue, in which the implant is configured to resist migration after implantation. The claimed invention relates to a flexible, helical coil, formed from a ribbon-like, flat filament that has an integral outer edge that defines a plurality of outwardly projecting barbs spaced along the edge. The barbs are adapted to engage the tissue into which the device is implanted to prevent the device from migrating from its implanted position under the influence of tissue movement.

Figs. 4 and 5, reproduced below, illustrate two embodiments.



**Fig. 4**



**Fig. 5**

The implants are formed from a flat, ribbon-like filament. The filament is formed to include an edge that is defined by a plurality of barbs spaced along the edge of the filament. The filament is wound into a helical coil with the barbs extending outwardly so that they can engage the tissue into which the device is implanted to prevent migration of the device. The barbs are an integral element of the filament. In the embodiment of Fig. 4, the turns of the coil are cantered such that the barbs 64 project outwardly. In the embodiment of Fig. 5, the barbs are bent to

project outwardly. Fig. 6, below, shows a flat sheet of material with multiple filaments etched on it and Fig. 7 shows a close-up view of one of the filaments. The coil can be made from a filament formed from a plurality of materials extending along the length of the filament, each having a different modulus of elasticity.

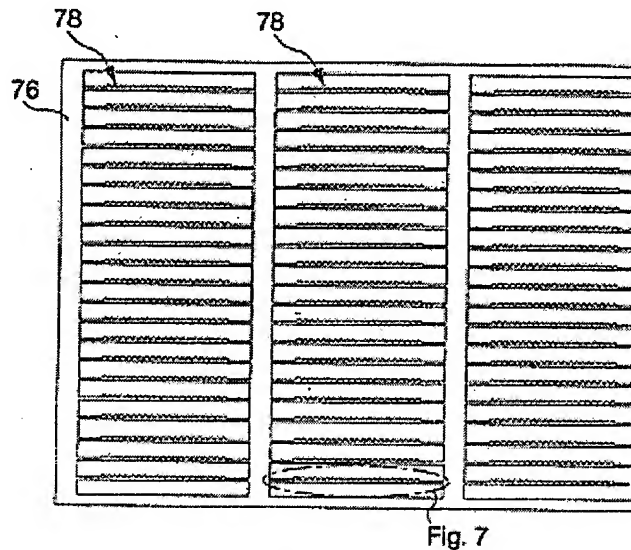


Fig. 6

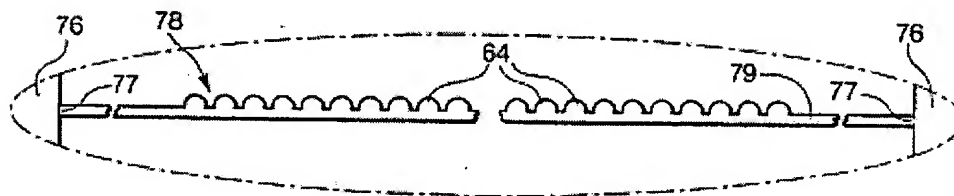


Fig. 7

#### **THE CITED ART**

##### **Smith (U.S. Pat. No. 6,364,904; "Smith")**

Smith relates to intraluminal stent grafts adapted to be placed within the lumen of a blood vessel and expanded into contact with the surface of the vessel lumen. As described in Smith, "[a] stent is a generally longitudinal tubular device formed of biocompatible material which is useful to open and support various lumens in the body." (1:23-26). A graft is another type of

common intraluminal prosthesis that provides an artificial lumen through which blood may flow. A common material for such grafts is expanded polytetrafluoroethylene (ePTFE). The stent/graft with which Smith is concerned combines the two in a stent/graft assembly. In the Smith arrangement, the graft is defined by a planar strip, for example, of ePTFE, and an undulating wire (which performs the stent function) and is attached along the length of the strip. The undulating pattern can be varied. One example is shown in perspective view in Fig. 3, below, and in cross-sectional view in Fig. 4, below.

FIG. 3

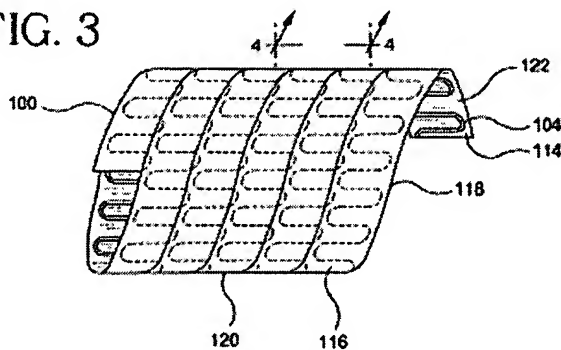
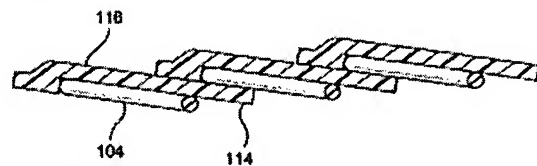


FIG. 4



The applied wire can extend out beyond the edges of the planar strip, as shown in Fig. 21, and the stent can be wound so that the stent wire protrudes beyond the planar strip (Fig. 22).

FIG. 21

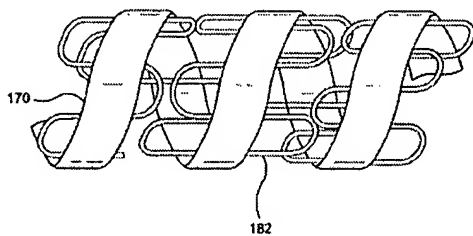
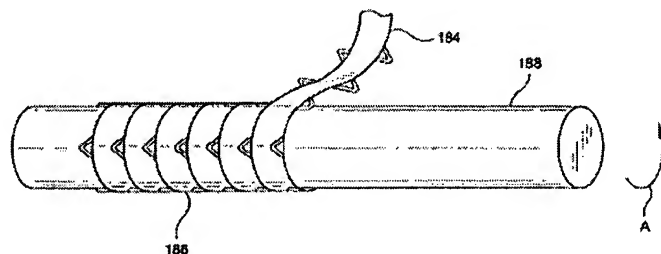


FIG. 22



## **THE REJECTIONS**

### **Claim Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 9 and 10 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds that there is insufficient antecedent basis, in claim 9 for the term “spring.” While applicant

acknowledges that there was no technical antecedent basis for the term "spring" in claim 9, that does not provide a basis for a rejection under 35 U.S.C. §12 (as compared to an objection). Accordingly, applicant traverses the rejection of claims 9 and 10 under 35 U.S.C. §112, second paragraph, as being indefinite. The asserted deficiency in the original claim, while perhaps not in the best form, was not such as to rise to a level of being indefinite and failing to satisfy 35 U.S.C. §112. The mere absence of a precisely technical antecedent basis for a term, where the scope and meaning of the claim would have been readily apparent to one of ordinary skill in the art, may warrant an objection, but not a rejection. Nonetheless, applicant has amended claim 9 to replace "spring" with --coil-- as used in claim 1 and from which claim 9 depends. The rejection should be reconsidered and withdrawn.

#### **Claim Rejections Under 35 U.S.C. § 102**

Reconsideration is requested of the rejection of claim 1 as anticipated by Smith (U.S. Pat. No. 6,364,904). Claim 1 has been amended to improve its syntax and also to define with further clarity that the plurality of outwardly projecting barbs are formed integrally with and are shaped to define the outer edge of the filament. Additionally, the filament is defined as being "flat" instead of having a "rectangular" cross-sectional profile. The flat configuration is described in the written description at page 6, line 9, original claim 12 and in the abstract (page 13, line 10).

Smith does not anticipate any of applicant's claims, first, because it discloses only an intraluminal stent graft, not a tissue implant and, second, because Smith fails to disclose a number of limitations in applicant's claims.

Applicant's invention relates to a tissue implant that is embedded within tissue and is configured so that it will resist migration within the tissue from dynamic action of the tissue (e.g., muscular tissue). Smith has no relation to the subject matter of applicant's invention. The Smith device serves to line the luminal surface of a vessel and is not implantable within tissue. It is, essentially, a support structure that serves as a scaffold to maintain the patency of a vessel lumen. It is not concerned with migration from an implanted position as a consequence of dynamic tissue movement.

Moreover, Smith does not disclose the claimed flat filament having an integral edge shaped to define a plurality of outwardly projecting barbs. To the extent that the rejection is based on the devices disclosed in Figs. 19-22 of Smith, they are a composite structure that combines a polymeric membrane and a wire-like stent that does not present the flat configuration claimed. To the extent that the Smith devices show portions of the undulating wire element extending beyond the edges of the polymeric sheet, they do not extend outwardly as claimed. There is no disclosure in Smith of any function or purpose for any portions of the wire that protrude beyond the edges of the polymeric sheet. Moreover, considering the nature of the Smith device in which it is to be placed within and against the luminal surface of a vessel, the presence of numerous barbs to secure the device in place would seem to present risks of damaging the delicate lining of the vessel. If any function was intended for the protruding elements of the undulating wire in Smith, there is no reason to assume, and it is not inherent that they were intended as the claimed barbs.

Accordingly, claim 1, particularly as amended, should not be considered as anticipated by Smith.

Claim 2 depends from claim 1 and is not anticipated by Smith for the same reasons. Additionally, claim 2 requires that the barbs, in addition to being outwardly projecting as called for in claim 1, also are proximally facing. Smith does not disclose the claimed barbs.

Reconsideration is requested of the rejection of claim 4 as anticipated by Smith. Claim 4 has been amended to define that the outer helical edge of the implant is shaped to define a plurality of integral outwardly extending barbs. As discussed above in connection with claim 1, Smith does not show the claimed integral shaped edge.

Claim 5 depends from claim 1 and adds the further limitation that the barb has a sharp point for engaging tissue. Smith does not disclose any particular function for those portions of the wire that protrude beyond the edge of the polymeric sheet. There is nothing in Smith from which one would reasonably conclude that Smith discloses barbs with sharp points, particularly in light of the endoluminal nature of the Smith stent/grfts.

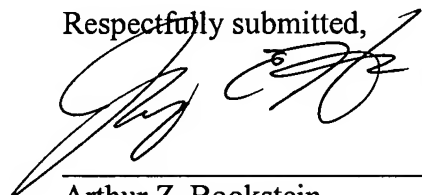
Claim 7 depends from claim 1 and is not anticipated by Smith for the same reasons.

Claim 8 also has been amended to reflect the flat filament having an integral edge shaped to define a plurality of outwardly extending barbs. This feature is not anticipated by Smith as discussed above. Additionally, claim 8 includes the limitation that the filament comprises a plurality of materials each having a different modulus of elasticity. Smith fails to disclose this additional limitation of claim 8. Claims 9-11 depend directly or indirectly from claim 8 and are not anticipated by Smith for the same reasons.

Method claim 14 has been amended in syntax as well as to specify that the barbs are an integral part of the ribbon and that the ribbon is wrapped so that the barbs project outwardly of the coil. As discussed above, Smith does not disclose these limitations of applicant's invention.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721, Reference No.: 0506765.0059.

Respectfully submitted,

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